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October 24, 2019

Via ECF

The Honorable Colleen McMahon
United States District Court
Southern District of New York
500 Pearl Street, Room 2550
New York, New York 10007

RE: *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-07488-CM-RWL

Dear Judge McMahon:

Plaintiffs write in response to Forest's October 23, 2019 letter ("Forest Letter") (ECF No. 901). As set out below, Forest's requests should be rejected because the issues raised in its letter have already been decisively addressed by the Court in Plaintiffs' favor, in some cases multiple times. Furthermore, Plaintiffs affirmatively request that the Court require Forest to stipulate to certain facts about Sun and Mylan's readiness to launch earlier in the But-For-World, consistent with Forest's statements at the pretrial conference and the stipulation that Forest has agreed to stipulate for two other generics.

Disclosures to the FTC and DOJ

For a third time, Forest seeks to resurrect whether it may introduce evidence or argument that it submitted the Lexapro Amendment to the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ"). Specifically, Forest seeks to introduce DTX-778, a letter from its lawyers at Davis Polk to the FTC and DOJ enclosing the Namenda patent settlement with Mylan and the Lexapro Amendment. DTX-778_001. The Court flatly rejected such evidence during the final pre-trial conference, after having already done so in its Order Disposing of Motions *in Limine*. See Tr. 72:1-2 (Oct. 10, 2019) ("403, probative value outweighed by potential for prejudice. End of story."); Order Disposing of Motions *in Limine*, ECF No. 859 at 18 ("Should [Forest] attempt to [introduce FTC or DOJ submissions], it will be foreclosed.").

Forest says that it wants to introduce DTX-778 to rebut the notion that they "hid" the terms of the reverse payment. Forest Letter, ECF No. 901; Tr. 67:7-11 ("if you are making a reverse payment you are not going to tell people."). That is a strawman argument, because as Plaintiffs have acknowledged (and the Court noted during the final pre-trial conference)

Plaintiffs are not arguing that Forest hid the Lexapro Amendment from the world. Tr. 65:19-21. (Oct. 10, 2019) (“Ms. Wilkinson, no one has said under-the-table, they have openly made the payment. The issue is what was the purpose of the payment, the real purpose of the payment.”).

But even if Plaintiffs were making this argument, Forest’s submission of the Namenda patent settlement and Lexapro Amendment to the FTC/DOJ would *not* prove that Forest disclosed those agreements to the world. Interestingly, in submitting those agreements to the FTC/DOJ, Forest specifically requested that they be treated as confidential for all purposes. *See* DTX-778 at 001-002 (“request[ing] that the Department of Justice and Federal Trade Commission treat the [Lexapro Amendment and Namenda patent settlement] as confidential under . . . 15 U.S.C. § 57b-2(c) and 16 C.F.R. § 4.10, and Section 1114 of Subtitle B of Title XI of the MMA,” which exempts MMA filings from disclosure under FOIA.).

Forest’s obvious purpose in seeking to use DTX-778 is to have the jury infer that by taking no action, the FTC and DOJ found no antitrust problem. The FTC, however, is very clear that “any suggestion by drug companies to courts *or others* that FTC inaction indicates that the agreement presents no antitrust problem would be *inaccurate and improper*.”¹ *See also* Pub. L. No. 108-173, 117 Stat. 2006 at 2463 (“any failure of the Assistant Attorney General or the Commission to take action[] under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant . . . under any other provision of law.”).

While Forest denied at the pretrial conference any intention to cause the jury to draw the impermissible conclusion that the FTC or DOJ “blessed” the agreements (Tr. 67-69), Forest’s recent conduct undercuts that assertion. For example, Forest has proposed to play video testimony from both Mylan’s lawyer and Forest’s lawyer that the agreements were not only submitted to the DOJ and FTC, but also that those agencies are charged with enforcing the nation’s antitrust laws, and those agencies never raised any objections to the settlement agreement. So Forest has proposed to use testimony from two witnesses to put the lack of DOJ or FTC objections squarely in front of the jury.

Moreover, Forest has objected to the redaction of text in the various generic patent settlements regarding FTC and DOJ review, and potential agency objections. Settlement terms concerning *prospective* obligations to submit MMA material to the FTC and DOJ are not probative of the ultimate “fact of” their submission, or probative of whether Forest engaged in a pay-for-delay deal with Mylan. *See* Forest Letter, ECF No. 901 at 3. If the ultimate “fact of” submission is truly what Forest is hoping to establish (and not the improper inference), then it should have no objection to redaction of those irrelevant terms. *See, e.g.,* Ex. 1 (exemplar settlement excerpts highlighting the text Forest has refused to agree to redact). Accordingly, in addition to reaffirming its Order disposing of Plaintiffs’ Mot. *in Limine* No. 9, and its clear ruling

¹ *See* FTC, Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003, https://www.ftc.gov/system/files/attachments/competition-policy-guidance/mma_pharmaceutical_agreement_filing_faq_6-6-19.pdf, last accessed Oct. 23, 2019. (Emphasis added.)

at the final pre-trial conference, the Court should also order the redaction of references to agency review from all documents to be used in this trial.

Further, the issue of disclosure to FTC/DOJ is irrelevant because whether the Lexapro Amendment was secret or public is not probative in this case of whether it was the vehicle through which Forest conveyed a reverse payment to Mylan. Your Honor suggested that Forest would certainly have disclosed to the world the Lexapro Amendment in a 10-K. Tr. 70:25-71:11 (Oct. 10, 2019). Interestingly, Plaintiffs have been unable to find any such public disclosure. Nevertheless, Forest could have shouted the terms of its reverse payment from the rooftops via a press-release, and filed it publicly with the SEC just like the defendants in *In re Niaspan Antitrust Litigation*. See, e.g., “Kos and Barr Announce Definitive Co-Promotion, Manufacturing, and Settlement Agreements.” (publicly disclosing reverse payments).² But doing so would have no impact on the ultimate issue in this case, which is whether the Lexapro Amendment was a large and unjustified payment to Mylan to drop its challenge to the Namenda patent.

The Court repeatedly recognized the irrelevance of whether a reverse payment was or was not disclosed, and also the improper and statutorily proscribed inference the jury would inevitably draw from evidence about Forest’s MMA submission. Tr.; 68:14-22 (“whether it got sent, I view, as having minimal probative value, the fact that they were sent to the F.T.C. and the Justice Department. So, the jury will undoubtedly wonder, well, did the F.T.C. or the Justice Department do anything in response to this? And the answer will be no . . . And the jury could very well think, well, then what could possibly be wrong with it?”).

While the Court initially discussed a possible stipulation concerning the fact-of Forest’s filing the Lexapro Amendment with the FTC and DOJ, it ultimately decided that there is no sense to such a stipulation, where the fact to be agreed-to “means nothing,” (*i.e.*, it has no evidentiary value under Fed. R. Evid. 402), but where its prejudicial impact is clear. Tr. 69:16; 72:1-2 (“403, probative value outweighed by potential for prejudice. End of story.”). Accordingly, Plaintiffs have declined to assent to the form of stipulation Forest proposed, and Forest’s proposed jury instruction (Forest Letter, ECF No. 901 at 3) would, in FTC’s words, be “inaccurate and improper.”

Finally, Plaintiffs would be remiss if they failed to point out that Forest’s intended use of DTX-778 seeks to use privilege as both a sword and a shield. At the final pre-trial conference, Forest’s counsel expressly injected attorney advice, arguing that “[*Forest*] ha[d] legal advice that said this would be better for you to do, it doesn’t require them to put the deal in.” Tr. 69:2-3 (Oct. 10, 2019) (emphasis added). Forest’s counsel was incorrect on the facts. Compare 117 Stat. at 2462 (requiring submission of agreements “otherwise related” to Hatch-Waxman settlements) to Tr. 66:23 (“Of course they’re linked.”). But inaccuracies aside, there is no surer way to waive privilege than to explicitly invoke advice of counsel. *Pearlstein v. Blackberry Ltd.*, No. 13-CV-07060 (CM)(KHP), 2019 U.S. Dist. LEXIS 45098, at *19-20 (S.D.N.Y. Mar. 19,

²<https://www.sec.gov/Archives/edgar/data/1018952/000095014405003858/g94486exv99w1.htm>, last accessed Oct. 23, 2019.

2019) (“A party cannot assert reliance on counsel as a defense . . . without waiving privilege.”) (collecting cases).

Plaintiffs explained to Forest’s counsel that in light of its express reliance on counsel to explain the purpose of DTX-778, Forest would have to waive privilege. Perplexingly, Forest responded by confirming that the letter represents its counsel’s subjective views about the requirements of the law. Ex. 2 at 2 (“Ms. Wilkinson was simply referring to DTX-778, which is a letter *from counsel at Davis Polk to DOJ/FTC stating that the Lexapro amendment did not need to be provided . . .*”) (emphasis added). Forest’s distinction, if there is one, makes no difference. Moreover, Ms. Wilkinson’s statement clearly did not simply invoke the statement made by Forest’s counsel in the letter to the DOJ/FTC, but rather her statement invoked the actual advice of counsel that Forest received. There is no way for Plaintiffs to test Ms. Wilkinson’s statement to the Court about that advice of counsel and the statement made by Forest’s counsel to the DOJ/FTC (DTX-778 at 001 -- “Although we [Davis Polk] *do not believe* that the following documents must be submitted . . .”) -- without reviewing the actual advice that Forest internally received from Davis Polk and possibly other lawyers.

References to Orchid’s Side Deal

The Court could not have been clearer that references to Namenda patent settlement side-deals other than the challenged Lexapro Amendment are out of the case. Specifically, at the final pre-trial conference, Forest’s Counsel argued that the jury could draw inferences from the fact that Orchid also received a “side-deal,” concerning the drug ceftaroline, in connection with its Namenda patent settlement. The Court firmly determined such evidence to be “403. It will [be] absolutely incomprehensible to the jury. Any probative value is outweighed by the – no. Forget it. It is not coming in. All right? It is not coming in.” Tr. 51:13-16 (Oct. 10, 2019). *See also id.* at 57:7-8 (“Orchid document so it is not going to come in, not admitted.”). Plaintiffs see absolutely no ambiguity in the Court’s determinations and we have accordingly asked Forest to agree to redact references to the ceftaroline “side deal,” which Fed. R. Evid. 403 clearly precludes, from PX-1534. The fact that Orchid signed a ceftaroline deal with its Namenda patent settlement has no bearing on whether the Lexapro Amendment was a large and unjustified reverse payment *to Mylan*.

Forest’s Proposed Claim Construction Summary

Plaintiffs cannot agree to Forest’s proposed 1006 claim construction summary exhibit because (1) it is directly contrary to both the Court’s ruling at the pretrial conference and Forest’s agreement to abide by that ruling; and (2) Defendants’ chart is inaccurate in various respects.

First, after considering the parties’ arguments at the pretrial conference, the Court ruled: “You can have Forest’s proposed construction, Mylan’s proposed construction, Court’s construction, period, the end, and you can make arguments from that.” Tr. 33:23-34:1. After unsuccessfully pressing for admission of the claim construction opinions, Forest agreed to “work with [Plaintiffs] on *such a chart*.” *Id.* at 34:25-35:1 (emphasis added). The chart that the Court ordered, and to which the parties agreed, is attached to Forest’s letter as “Ex. C, DPPs’ Proposed 1006 Claim Construction Chart.” It includes the very three columns – “Forest Proposal,”

“Mylan Proposal,” and “Adopted Construction” – that the Court ordered; nothing more and nothing less.

Forest’s argument that the jury cannot learn the “actual [claim construction] language from the underlying court orders” (Forest Letter, ECF No. 901 at 2) is a non-sequitur. The Court’s ruling at the pretrial conference was that the chart would include a column with the “Court’s construction.” Tr. 33:23-34:1. According to Forest, the jury cannot learn the construction adopted by Judge Sleet because this Court held that “not a word of the [claim construction] opinion is going to come in.” *Id.* 33:23-24. Forest has confused the concepts of an inadmissible claim construction “opinion” explaining the reasoning for a court’s decision and the admissible claim construction “order” merely setting forth the adopted constructions of claim terms. Judge Sleet’s claim construction “order” – as opposed to his inadmissible claim construction “opinion” – is already in evidence as PX-1400. Moreover, there was never any discussion – nor any agreement by Plaintiffs – to include a column corresponding to the report and recommendation or a particularly confusing column titled “Appeal?” as reflected in Forest’s proposed chart.

Forest’s recognition that Judge Sleet’s claim construction was an albatross around its neck in the underlying patent litigation is nowhere more clearly exposed than Forest’s statement that “[t]he precise language that Judges Stark or Sleet used in their opinions is not material for purposes of what the jury must decide.” (Forest Letter, ECF No. 901 at 2). If Forest truly believed the adopted claim constructions favored its interests, Forest would of course immediately endeavor to include them, rather than affirmatively seeking to exclude them, from the summary chart.

Second, Forest’s proposed claim construction summary exhibit is also unacceptable because it is riddled with inaccuracies in Forest’s favor. In drafting their proposed chart, Plaintiffs’ relied on (1) Forest’s claim construction brief for the chart column titled “Forest Proposal” (Namenda Patent Litigation ECF No. 223, attached as Ex. 3); (2) the generics’ claim construction brief for the chart column titled “Mylan Proposal” (Namenda Patent Litigation ECF No. 222, attached as Ex. 4); and (3) Judge Sleet’s claim construction order (PX-1400) for the chart column titled “Adopted Construction” (PX-1400 and Namenda Patent Litigation ECF No. 426, attached as Ex. 5). Forest has not disputed the accuracy of Plaintiffs’ proposed chart entries, as reflected on Forest’s Ex. C.

In contrast, as Plaintiffs have twice told Forest, the entries in Forest’s chart (Forest’s Ex. B) contain inaccuracies. 10-21-2019 Email (attached as Ex. 6) (correcting cell entries in Forest’s proposed chart); 10-23-2019 Email (attached as Ex. 7) (reminding Forest that there are “inaccuracies” after Forest failed to address them following the 10-21-2019 email). But in its zeal to portray the final claim construction as a “win,” Forest has introduced – and refused to correct – these numerous inaccuracies. For example, regarding the term “treatment of Alzheimer’s disease,” Forest’s chart is an outright mischaracterization. Forest’s chart represents that Forest proposed “treatment of cerebral ischemia after Alzheimer’s disease” and that Judges Stark and Sleet “adopted Forest’s construction.” Forest Ex. B at 4. In actual fact, Judge Sleet rejected Forest’s proposal, ruling that the term would “incorporate[] by inference” his construction of “Alzheimer’s disease” but otherwise receive its “plain and ordinary meaning.”

PX-1400 at 2. Accordingly, Judge Sleet outright refused to adopt Forest's proposal to include the concept of "cerebral ischemia" in the term. Similarly, for the term "effective amount," Forest misstates its own proposed construction, which actually included the word "treatment" at the end. Namenda Patent Litigation ECF No. 223 at 40. Forest's proposed construction was ultimately modified to remove the term "treatment." PX-1400 at 2. As a result, the statement in Forest's proposed chart that Judges Stark and Sleet "adopted Forest's construction" is not accurate (although Judge Stark purported to adopt Forest's proposed construction in DX-15 at 26-27). As yet another example, Forest's chart reflects that for the terms "prevention of cerebral ischemia" and "amount effective to prevent degeneration and loss of nerve cells after ischemia," Judge Stark and Judge Sleet "Adopted Neither Party's Construction" but provides zero insight into what construction they did adopt, and therefore is not helpful in any respect to the jury.

There are numerous additional errors and problems in Forest's chart, which Plaintiffs can provide if desired.

Forest Should Be Required to Enter into Ready-to-Launch stipulations for Sun and Mylan

During the final pretrial conference, the Court observed, and Forest agreed, that the issue of generic manufacturers being earlier ready to launch in the but-for world was not a contested issue in the case. *See* Tr. 18:23-19:11 ("THE COURT: I didn't really think there was an issue about ready to launch. MS. WILKINSON: Right. * * * THE COURT: There are things that you can stipulate to. That was the one that really occurred to me, was ready to launch. MS. WILKINSON: Yes. We'll talk after court today and see what we can come up with.").

While Forest agreed during the pretrial conference to stipulate to these issues, Forest has reversed course and refused to stipulate the issue entirely out of the case. For two generics (DRL and Amneal), for which there would be live testimony, the most that Forest will agree to are fact stipulations (finalized and soon to be signed and presented to the Court) that distill their testimony into about a dozen facts each, that the Court can read to the jury. Having eliminated the live witnesses, for two other generics (Sun and Mylan), Forest refuses to enter into similar stipulations, and will instead require that their videotaped testimony be played to the jury. While Forest explains that video is not a burden to the witnesses, Plaintiffs' view is that it is a burden to the jury and the Court to lengthen this trial on an issue that Forest previously agreed is not genuinely contested. The Court should require Forest to enter into ready-to-launch stipulations for Sun and Mylan, and should consider holding Forest to its earlier commitment and require the parties to stipulate the issue out of the case altogether.

Respectfully,

/s/ Bruce E. Gerstein
Bruce E. Gerstein